

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ROCHE DIAGNOSTICS GMBH, *et al.*,

Plaintiffs,

-v-

ENZO BIOCHEM, INC., *et al.*,

Defendants.

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No. 04 Civ. 4046 (RJS)
ORDER

RICHARD J. SULLIVAN, District Judge:

The Court is in receipt of the attached joint letter submitted by Enzo Biochem, Inc., Enzo Life Sciences (together with Enzo Biochem, Inc., “Enzo”), Roche Diagnostics GmbH, and Roche Molecular Systems, Inc. (together with Roche Diagnostics GmbH, “Roche”). Enzo seeks to strike supplemental invalidity contentions that Roche filed after the relevant deadline and to compel production of licenses, consumer agreements, and sales and financial information related to certain Roche products. The Court will address Enzo’s requests in turn.

I. BACKGROUND

On February 7, 2013, the Court issued a Scheduling Order that called for infringement contentions by Enzo “on or before April 15, 2013” and invalidity contentions from Roche “on or before May 17, 2013.” (Doc. No. 99.) Notably, Roche proposed the deadlines for infringement and invalidity contentions and reminded the Court that the “benefits of exchanging infringement contentions early in the discovery period cannot be seriously contested: Early contentions ‘force parties to crystallize their theories early in the case,’ ‘to identify the matters that need to be resolved,’ and to ‘streamline discovery by mandating the disclosures that are core to patent cases,

thus reducing the need for interrogatories, document requests, and contention depositions.” (Jt. Letter from Enzo and Roche, dated Feb. 5, 2013, at 5, 5 n.4 (quoting Federal Judicial Center, *Patent Case Management Guide* 2-9, 5-6, 5-7 (2009)).)

After those important early deadlines passed, on June 11, 2013, the Court ordered the parties to apprise the Court of the status of discovery, including the parties’ progress toward interim deadlines. (Doc. No. 114.) The parties submitted a letter on June 18, 2013, explaining that they “believe[d] that discovery [was] proceeding on pace and expect[ed] to meet all of the deadlines set forth in the Court’s Scheduling Order.” (Jt. Letter from Enzo and Roche, dated June 18, 2013, at 1.) The parties have since requested and received short extensions of the discovery deadlines set by the Court (Doc. Nos. 115, 123), but at no time have they sought to extend the time for filing contentions or sought leave to make supplemental contentions submissions. Accordingly, the time for infringement and invalidity contentions concluded in spring 2013, fact discovery closed October 21, 2013, and briefing for claim construction will begin November 15, 2013.

II. SUPPLEMENTAL INVALIDITY CONTENTIONS

Although the time for infringement and invalidity contentions has long passed, the parties have both sought to supplement their contentions. On September 5, 2013, the parties submitted a joint letter in which they disputed whether Enzo could seek discovery for products that were not listed in its April 15, 2013 infringement contentions. In light of the age and history of this case, the Court ruled that Enzo “failed to accuse [those products] in the operative document that list[ed its] infringement contentions,” and that Enzo could not “proceed with an infringement case against products [it] did not accuse.” (Doc. No. 122 at 3; *see* Doc. No. 120 at 2.) Now Roche seeks to supplement its invalidity contentions, but the same rule applies: The Court will

not permit Roche to posit new invalidity contentions after the May 17, 2013 deadline. Enzo has not been permitted to add new infringement contentions, and Roche will not be permitted to supplement its invalidity contentions. If Roche needed more time to research or respond to Enzo's accusations, then it should have sought an extension before the May 17, 2013 deadline – an interim deadline Roche emphatically advocated – or at the very least before now, nearly half a year later. Accordingly, IT IS HEREBY ORDERED THAT Enzo's motion to strike Roche's supplemental contentions is GRANTED.¹

III. DISCOVERY DISPUTES

The parties also dispute whether Roche should be compelled to produce licenses and agreements related to the Elecsys/ECL products accused of infringing the '523 patent. The discovery standard is broad, and Enzo is entitled to "discovery regarding any nonprivileged matter that is relevant to" its claims or defenses even if the discovered material is "not . . . admissible at the trial [so long as it] appears reasonably calculated to lead to the discovery of admissible evidence." Fed. R. Civ. P. 26(b)(1). The Court concludes that licensing agreements for Elecsys/ECL-related products and reagent/instrument agreements for Elecsys-related products meet this broad standard. Accordingly, IT IS FURTHER ORDERED THAT Roche shall produce this discovery.

¹ The Court notes that Roche relies on *Alt v. Medtronic*, No. 2:04 Civ. 370 (LED), 2006 WL 278868, *5–6 (E.D. Tex. 2006), for the proposition that the Court would be justified in permitting supplemental invalidity contentions even though it previously denied supplemental infringement contentions. *Medtronic* is different than this case. There, the Court was dealing with requests for supplemental contentions *after* the claim construction hearing, and the court reasoned that the "addition of prior art references post *Markman* do not have the same implications upon *Markman* briefing and arguments as the addition of a patent claim," which would result in irreparable prejudice to the defending party. The posture of this case is different, and the Court's rationale is different. The Court has taken a firm position on the deadlines imposed by its Scheduling Order, and neither party sought to amend that Order with respect to contentions. Because more than five months has elapsed since the relevant deadlines, the Court rejects the argument that there is good cause for either party to raise additional contentions.

Enzo also mentions that “Roche has failed to produce financial/revenue information for the Elecsys e170 instruments and/or for the first few years of infringing sales after launch (i.e., pre-2000).” From this vague statement, the Court is clearly not in a position to determine whether Roche has withheld relevant discovery with regard to financial or revenue information. Accordingly, IT IS FURTHER ORDERED THAT Roche need not produce financial or revenue information unless Enzo demonstrates the relevance of such information to Enzo’s claims or defenses or that the information is likely to lead to admissible evidence at trial.

IV. CONCLUSION

For the reasons set forth above, Enzo’s motion to strike Roche’s supplemental invalidity contentions is granted, as is its motion to compel production of licenses and agreements relating to the Elecsys/ECL products accused of infringing the ‘523 patent. Enzo’s remaining discovery requests are denied.

SO ORDERED.

DATED: November 11, 2013
New York, New York



RICHARD J. SULLIVAN
UNITED STATES DISTRICT JUDGE

November 5, 2013

BY E-MAIL (sullivanysdchambers@nysd.uscourts.gov)

Honorable Richard J. Sullivan, U.S.D.J.
United States District Court
Southern District of New York
500 Pearl St., Room 615
New York, NY 10007

Re: *Roche Diagnostics GMBH et al. v. Enzo Biochem, Inc. et al.*
No. 04 CV 4046 (RJS) (S.D.N.Y.)

Dear Judge Sullivan:

Pursuant to the Court's Individual Practices § 2.G, the parties to the above-referenced action jointly submit this letter concerning Enzo's request to: (i) strike Roche's supplemental Invalidity Contentions and preclude reliance thereon in this action; and (ii) compel production of certain Roche licenses, customer agreements, and sales/financial information which Enzo contends to be relevant to infringement, damages and validity/success of the patented invention. Counsel for Enzo (Richard Pettus, Jonathan Ball, Jennifer Moore) and Roche (Robert Gunther, Jr., Omar Khan, Ryann Muir, Cyndy Chueh) met and conferred on September 20, October 7, 10, 21 and 22 concerning these issues, but have been unable to resolve them.

I. Enzo's Position

A. Roche Should be Precluded from Reliance on Unjustifiably Late Invalidity Contentions Adding Nearly Sixty (60) New Prior Art References and Defenses

After fighting so hard to preclude Enzo from supplementing its Contentions in 'his patent infringement proceeding -- and obtaining a ruling that contentions served after the scheduled date will not be permitted to proceed (D.I. 120 at 2; *see also* D.I. 122 at 2-3) -- Roche now seeks to vastly expand its Court-ordered Invalidity Contentions by adding almost sixty (60) new prior art references and more than a half dozen new invalidity theories under 35 U.S.C. § 112. ("the Late Contentions," *see* Ex. A at 5-6, 8-9; Ex. B at 7-8, 14-16; Ex. C at 8-11; Ex. D at 9.) Per the Court's Order, Roche was to provide Invalidity Contentions by or before May 17, 2013, that *inter alia*, identified, "each item of prior art that the party contends allegedly anticipates or renders obvious each asserted claim," (D.I. 99 § 7(b), emphasis added) as well as "any other grounds of invalidity, including any under 35 U.S.C. § 101 or § 112, or unenforceability of the asserted claims." (*Id.*) Having had nearly *eight years* to identify its prior art references and invalidity positions (from publicly available sources),¹ Roche served new invalidity contentions

¹ Roche gave no "good cause" or other justification for its untimely and vastly expanded Invalidity Contentions during the prolonged weeks-long meet and confers on this issue. Instead, Roche promised for weeks to propose a "deal" to avoid Enzo's motion to strike/preclude but ultimately never did so. Roche's attempt to now argue that most (i.e., 44) of the newly-added prior art references are just "background," is highly misleading in view of Roche's clear statements in the Late Contentions that all of "the prior art references cited in its Late Contentions, either alone or in combination with other identified references, anticipate and/or render obvious" the asserted claims of the

on September 17, September 30 and October 16, 2013, months after the date set by the Court and the original close of fact discovery. There is no plausible excuse for Roche's lack of diligence, and what amounts to a doubling of its Contentions more than five months after they were due. See *O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1366 (Fed. Cir. 2006).² Roche's disclosure of these Late Contentions is highly prejudicial, forcing Enzo to undertake the claim construction process without time for strategic/technical evaluation of and consultation on them, and after Enzo had already deposed Roche's technical witnesses in Germany without the opportunity to consider Roche's late-identified prior art references and defenses.³ See *Convolv, Inc. v. Compaq Computer Corp.*, 2006 WL 2527773, at *6 (S.D.N.Y. Aug. 31, 2006). It would also be highly unfair to permit Roche to unreasonably delay without good cause and vastly expand its Court-ordered Contentions, particularly after it so vehemently lobbied to restrict Enzo to its initial Contentions. Having proposed the scheduled deadlines for contentions which were adopted by the Court, Roche knew when its Contentions needed to be served, and it was incumbent upon Roche to investigate, prepare and deliver them prior to that date, so Roche's acknowledgement that it "conducted additional prior art searches through its outside experts after serving its invalidity contentions" (two months earlier) does not justify, but rather confirms the untimeliness of the Late Contentions and Roche's lack of diligence. Enzo requests that the Late Contentions be stricken and that Roche be precluded from relying on any of the new prior art references and new grounds of invalidity under Section 112 or otherwise in this action. See *CoreLogic Info Solns., Inc. v. Fiserv, Inc.*, 2012 WL 4051823, at *3 (E.D. Tex. Sept. 13, 2012).⁴

patents. (Ex. A at 2, 6-7; Ex. B at 2, 9; Ex. C at 2; Ex. D at 2.) If Roche does not intend to use any of the 44 new references as prior art of their invalidity arguments then there is no reason under the rules for them to be included in the contentions. Either way, Enzo asks that Roche's Late Contentions be stricken.

² Roche was aware of several of the late-identified references before its May 17 Contentions were served but did not include them (e.g., RE842868-76; RE844223-44; RE803252-66). Production amongst thousands of other documents and general reservations of right to rely on more prior art, however, is insufficient to satisfy its Invalidity Contention obligations. *Cummins-Allison Corp. v. SBM Co.*, 2009 WL 763926, at *4 (E.D. Tex. 2009).

³ Roche's argument that Enzo failed to ask Roche's witnesses about the prior art neglects to mention that Roche objected to and refused to produce a 30(b)(6) witness on this Topic (see Ex. H, No. 6) as well as that Roche's first set of Late Contentions were provided the night before the September 18th Roche depositions in Germany began with the even-later contentions following weeks later.

⁴ Enzo disputes Roche's assertion that Enzo was not diligent in accusing the precluded Taqman products (which it formally did in 2007) and/or clarifying its Contentions shortly after Roche first revealed it was contesting the issue. The fact is, unlike Roche's Late Contentions, Enzo's April infringement contentions were reliant on Roche's confidential technical information which Roche now admits it did not produce until over a month after Enzo's infringement contentions were due (and was produced amongst 250,000 pages of other documents). Enzo also disputes Roche's further assertion that it would have been prejudiced by limited damages discovery on Taqman, especially when months later Roche has yet to complete damages discovery on other accused products. In any case, Enzo's activities are wholly irrelevant to the question at-bar, i.e., why Roche failed to exercise diligence with respect to its Court-ordered May 17 Contentions. Notably, Roche fails to specifically identify a single change in Enzo's Contentions that would justify its three amendments, months later, to add a voluminous number of references and defenses into the case.

B. Roche Should Be Ordered to Produce Financial and Other Documents Relevant to Patent Infringement, Damages and Success of the Invention

Despite Enzo's repeated requests, Roche has refused to produce relevant discovery and/or failed to abide by its commitments to do so. Discovery is broad under the federal rules and parties may obtain discovery regarding any matter relevant to its claims and defenses. *See* Fed. R. Civ. P. 26(b)(1); *Chembio Diagnostic Sys., Inc. v. Saliva Diagnostic Sys., Inc.*, 236 F.R.D. 129, 135 (E.D.N.Y. 2006). Yet, Roche has unjustifiably refused to produce license and other agreements relating to the Elecsys/ECL products accused of infringing the '523 patent (*see* Ex. E, No. 79; Ex. F, Nos. 30 and 35; Ex. G, Nos. 13, 40, 43-44, 84-86, 90, 96-97, 103-104). Roche's documents and recently-deposed 30(b)(6) witness confirm that Roche has improperly withheld license agreements with at least Brahms, Eisai, RSR, CanAg, RCT, Bayer, Centocor (Horsch Tr. 84, 115, 157; RE0404908-17) relating to royalties paid by Roche for the manufacture, use and sale of the accused Roche "Elecsys/ECL"-related products, as well as reagent/instrument agreements with Elecsys customers (Horsch Tr. 50:4-8; RE3450183). These agreements and associated financial/revenue information, including for any and all of the Elecsys instruments (1010, 2010, e170, etc.), are unquestionably relevant as confirmed by the admissions of Roche's 30(b)(6) witness that an Elecsys user "needs the instrument to run the assays" and that "no other competitor...supplies an instrument that could be run with [Roche's] Elecsys assays" (Ofenloch Tr. 24-25) to the issue of infringement/damages (reasonable royalty on sales revenue, convoyed sales, etc.) and the commercial value and success of the invention. *See Chembio*, 236 F.R.D. at 137-139 (E.D.N.Y. 2006). For instance, Roche has failed to produce financial/revenue information for the Elecsys e170 instruments and/or for the first few years of infringing sales after launch (i.e., pre-2000). *Id.* Enzo seeks immediate production of this improperly withheld discovery.

II. ROCHE'S POSITION

A. Unlike Enzo, Roche Was Diligent In Supplementing Its Contentions And It Did So Well Before Any Prejudice To Enzo Or The Schedule Could Materialize.⁵

The issue before the Court is whether good cause supports Roche's supplemental invalidity contentions. *See* Local Patent Rule 9; Patent Case Management Judicial Guide, § 2.2.3.3.1 (2d ed. 2012).⁶ As a threshold matter, the Court should reject Enzo's effort to draw parallels to the denial of discovery relating to Roche's Taqman® probes. *See Alt v. Medtronic*, 2006 WL 278868, *5-6 (E.D. Tex. 2006) (allowing amended invalidity contentions after previously denying amended infringement contentions). In its September 5, 2013 letter to the Court, Enzo *did not even attempt to argue* that it was diligent in supplementing its contentions to include the Taqman® probes.⁷ Nor did Enzo dispute the fact that its supplemental contentions would have been prejudicial insofar as they would have rendered it impossible to meet the

⁵ During the meet-and-confer on this issue, Enzo expressed no interest in hearing Roche's reasons for supplementing its contentions and instead stated, in unequivocal terms, that Enzo would seek to strike Roche's contentions.

⁶ District courts typically consider the factors set forth in *Convolve*, 2007 WL 700904, at *2 (S.D.N.Y.2007).

⁷ Enzo could not have made any such argument. As explained in the parties' submissions to the Court, Roche produced a complete set of technical documents relating to the TaqMan® probes in May 2013. Enzo did not seek to supplement its infringement contentions until four months later, at a time when allowing Enzo to accuse an entirely new product line would have jeopardized the entire schedule and required the parties to start from square one.

deadline for the close of fact discovery without compromising Roche's defenses to Enzo's new infringement theories. By contrast, Roche's supplemental invalidity contentions are fully justified for three separate reasons and, accordingly, the Court should deny Enzo's request for the "drastic" and "extreme" remedy of precluding critical evidence of patent invalidity when neither party is seeking any additional fact discovery on the issue.⁸

First, Enzo progressively expanded the scope of its infringement and claim construction theories over the course of discovery, which implicated a much higher volume of prior art, necessitated additional searching, and required revisions to Roche's invalidity positions.⁹ See *Fresenius Medical Care v. Baxter Intern.*, 2005 WL 2043047 at *2 (N.D. Cal. 2005) (shifting infringement theories relevant). Supplementation was also justified by the nature of the prior art investigation itself, which was extremely laborious and time consuming. Because the asserted patents are directed to certain chemical structures, prior art cannot be readily located based on the use of standard search terms or electronic searches. Thus, through its outside experts, Roche conducted additional prior art searches after serving its initial invalidity contentions to make sure that any relevant prior art had been captured, a task made even more complicated by Enzo's expanding view of the patents. *Advanced Micro Devices v. Samsung*, 2009 WL 890515 at *1-2 (N.D. Cal. 2009) ("lack of standardized terms" and "high volume" of prior art relevant).

Second, Roche's supplemental contentions neither prejudiced Enzo nor impacted the case schedule. Enzo has never sought, and it does not now seek, any additional discovery relating to Roche's contentions. Enzo did not ask Roche's witnesses *a single question* about Roche's invalidity positions, and Enzo *does not now seek to redepose* those witnesses.¹⁰ All but one of Roche's invalidity arguments were disclosed in contentions served prior to the parties' meet-and-confer on claim construction, which was the first step in that process. Enzo does not identify any implications that Roche's supplemental contentions would have on Enzo's claim construction positions, nor does Enzo suggest that it cannot address any such implications in its proposed constructions and/or in its opening claim construction brief due on December 20.¹¹ See *Samsung*, 2009 WL 890515 at *2; *Tessera v. AMD*, 2007 WL 1288199, *1 (N.D. Cal. 2007).

Third, the record makes clear that Roche timely supplemented its invalidity contentions when it became aware of additional relevant prior art and invalidity arguments:

⁸ See *Abbott Labs. v. Lupin*, 2011 WL 1897322 (D. Del. 2011) ("extreme sanction" under the circumstances); *Bristol-Myers v. Rhone-Poulenc*, 2000 WL 1154056 (S.D.N.Y. 2000) ("little, if any, fact discovery required").

⁹ Enzo's amended infringement contentions and interrogatory responses, which were served on August 29, September 12, 14, and 15, take an extremely broad view of the patent claims. For example, in footnotes 3 and 4 of its September 12, 2013 contentions, Enzo accused "all products" with a detectable molecule and a "linker having at least 6 atoms with at least 4 atoms in a direct chain." At page 10 of its September 14 contentions, Enzo effectively construed the "A³" claim limitation in the '523 patent as *any* sequence of atoms attached to a "NH-CH₂" sequence.

¹⁰ That Roche did not offer a 30(b)(6) witness on its invalidity contentions is irrelevant. Enzo also did not provide a 30(b)(6) witness on such issues, which are typically the province of experts. Also, Roche's witnesses were noticed in their individual capacities, which means that Enzo could have asked those witnesses any questions it wanted.

¹¹ Enzo's other arguments are equally meritless. That this case has been ongoing for eight (8) years is not relevant because the '523 patent claims were stayed until February 28, 2013, and because Roche could not provide comprehensive invalidity contentions without knowing Enzo's infringement theories. It is also irrelevant that Roche's supplemental invalidity contentions are based on public materials, because, almost by definition, prior art is based on knowledge in the public domain. Enzo's "circular view" would effectively mean that invalidity contentions could never be supplemented. *Positive Techs. v. Sony Elec.*, 2013 WL 322556, *2-*4 (N.D. Cal. 2013).

- Roche supplemented its contentions with three (3) prior art references and five (5) invalidity arguments based on discussions with its technical experts in late July and August. Roche supplemented its contentions with those positions on September 17, before Roche's depositions and/or the claim construction phase.¹² The *only* reason Roche did not immediately supplement its contentions is that Enzo refused to respond to Roche's requests for a date to exchange responses to contention interrogatories, *see* September 5, 2013 Letter to the Court at 3-4, which the parties eventually agreed would be in mid-September.
- Roche further supplemented its contentions with nine (9) prior art references on September 30, and seven (7) invalidity arguments on September 17, September 30, and October 16.¹³ Over that timeframe, Roche learned through Enzo's supplemental infringement contentions and interrogatory responses that Enzo was intending to take an extremely broad view of the patents, thereby implicating additional prior art and invalidity arguments. *See supra* note 9.
- Three (3) references in Roche's September 17 contentions—Heller, Whiteley and Guesdon—were produced in connection with Roche's December 2005 invalidity contentions relating to other Enzo patents not at issue here. Although Roche was aware of those references in 2005, with respect to the '830 and '523 patents at issue here, their "materiality . . . only became apparent after the invalidity contentions were filed." *Tessera*, 2007 WL 1288199, at *1.
- Enzo's assertion that Roche added "nearly 60" references is misleading because, as Roche made clear in its interrogatory responses, forty-four (44) of those references were cited as background materials that do not "themselves constitute prior art." *See REC v. Bamboo*, 2012 WL 3527891, at *4 (W.D. Wash. 2012); Local Patent Rule 7. The Court need not address those references because Roche was not required to list them in its contentions but did so anyway to provide more complete disclosure of its theories. *See* Exs I, J (highlighted).¹⁴

B. Enzo's Request For Additional Discovery Should Be Denied.

In July 2013, Roche produced a comprehensive set of licenses and agreements relating to the asserted patents. After the deposition of Roche's 30(b)(6) witness on licensing topics and the twice extended deadline for the close of fact discovery, Enzo now seeks dozens of licenses and thousands of customer agreements based solely on the ground that they "relate" to the accused products. The Court should reject Enzo's request because Enzo has not made any argument that the additional agreements it seeks are related to the asserted patents and/or the features of the accused products that relate to the claimed inventions. *See Funai v. Orion*, 2002 WL 1808419 at *15-16 (S.D.N.Y. 2002). With respect to "associated financial/revenue information," it is unclear what specific, additional discovery Enzo is seeking because Roche has conducted a reasonably diligent search and produced all responsive financial documents it discovered.

¹² These are the Costello, Gallati, and Wagener references cited in Roche's invalidity contentions, as well as the '523 patent invalidity arguments based on the terms "structural protein" in claim 13, "detectable metal chelatable thereby" in claim 15, "a detectably labeled specific [binding] partner" in claim 15, and "the molecule of claim 15" in claims 16, 18, and 20, and the '830 patent invalidity argument based on the term "non-radioactive moiety."

¹³ These are the additional prior art references cited in Roche's September 30 contentions, as well as the '523 patent invalidity arguments based on the claim terms "A²," "Det^b . . . comprising," and "A¹," and the '830 patent invalidity arguments based on the claim terms "oligo- or polynucleotide," "indirectly attached," and "terminal nucleotide"

¹⁴ Roche's contentions expressly state that the cited references "may be relied upon to show the state of the art in the relevant time frame," which, for forty-four (44) of the references, Roche confirmed in its interrogatory responses.

Honorable Judge Richard J. Sullivan
November 5, 2013
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Respectfully submitted,

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